UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

THIRD PARTY PAYOR TRIAL PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

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I. INTRODUCTION

The TPP Trial Defendants' ("Defendants") Motions for Summary Judgment (ECF 2562, 2564, 2565, 2570)[1] ignore the basic facts surrounding Defendants' manufacture and sale, and eventual recall, of millions of prescription pills sold by Defendants as FDA-approved valsartan. (*See, e.g.*, Defs.' Omnibus Mot., at 1 ("***alleged*** presence of [NDMA and NDEA]" (emphasis added)).[2] In fact—and as demonstrated in Plaintiffs' affirmative summary judgment submissions—*every single pill* sold by Defendants was contaminated with NDMA and/or NDEA, which are classified as probable[3] human carcinogens and which the FDA in its guidance on genotoxic impurities specifically singled out as in a "cohort of concern" of "high potency mutagenic carcinogens."[4]

Defendants' legal arguments are similarly disingenuous, as they ignore and/or attempt to re-litigate decisions rendered by this Court on issues that include but are not limited to: general causation (*see* Defs.' Omnibus Mot., at 5-6 (arguing that the

[1] For ease of reference, Defendants' Omnibus Motion will be referred to herein as the "Motion" and the Defendant-specific Motions will be referred to as the "ZHP Motion," "Teva Motion," and "Torrent Motion," respectively.
[2] Plaintiffs' hereby incorporate their objection to Defendants' reliance on their experts to support facts in their SOMF. (*See* Pls.' Opp. to Defs.' SOMF Footnote 6).
[3] Researchers are so confident that these are human carginogens that it is considered unethical to conduct human studies to confirm. *See, e.g.*, Pls.' Affirmative ZHP SOMF ¶ 139, 163.1 [hereinafter "ZHP SOMF"].
[4] ICH M7 Guidance. *See, e.g.*, ZHP SOMF ¶ 57-58, 61, 85-87, 130-131; Pls.' Affirmative Teva SOMF ¶ 98-100, 102 [hereinafter "Teva SOMF"]; Pls.' Affirmative Torrent SOMF ¶ 52-53 [hereinafter "Torrent SOMF"].

cancer risk "was extremely low")), pre-suit notice (*id.* at 8-10), whether certain of Defendants' statements regarding their VCDs constituted warranties (*id.* at 16-18), and damages issues (*id.* at 21-43).

Defendants also continue to assert that their VCDs had economic "value" because of Defendants' contention they treated blood pressure effectively. Aside from ignoring that no purchase would or could have happened in the absence of the representations that this was the approved compliant formulation, Defendants offer no competent evidence to support that contention (the Court has struck all of Defendants' liability experts who have attempted to make such arguments (Dr. John Flack, *see* ECF 2581, at 12; Dr. Punam Keller, *see* ECF 2261, at 77-79).[5] Further, this Court already ruled at least three times that Plaintiffs have suffered concrete, compensable injury. Defendants' Omnibus and Defendant-specific Motions for Summary Judgment should be denied.

[5] Plaintiffs intend to file a motion *in limine* to preclude Defendants from offering evidence of the efficacy of their VCDs, as that is irrelevant to the claims. *See, e.g.,* ECF 775, at 20 ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure.").

II. LAW AND ARGUMENT[6]

A. Defendants' Express Warranty Arguments Should Be Rejected (Again)

Plaintiffs' Express Warranty claims for this class trial (namely, Subclass Group b[7]), were properly filed.

1. The Court Should Find State Law Pre-Suit Notice Requirements Inapplicable in Federal Court Under Hanna and Shady Grove

State law pre-suit notice requirements are inapplicable in federal court as conflicting with the Federal Rules of Civil Procedure pursuant to *Hanna v. Plumer*, 380 U.S. 460 (1965), and *Shady Grove Orthopedics Associates, P.A. v. Allstate Insurance Company*, 559 U.S. 393, 410 (2010). Under *Hanna* and *Shady Grove*, the threshold question is (1) whether there is a conflict between the state law and the Federal Rule, and (2) whether the Federal Rule(s) at issue are valid. *Albright v. Christensen*, 24 F.4th 1039, 1048-49 (6th Cir. 2022).[8]

Obliging litigants to commence proceedings with pre-suit notices to the

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[6] Nothing herein should be construed to forfeit or otherwise undercut Plaintiffs' arguments that they are affirmatively entitled to summary judgment on the claims. *See* ECF 2569.

[7] The States included are Alabama, Arkansas, Florida, Georgia, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin, and Wyoming. ECF 2532-6 (Pls' Mot. for Class Notice TPP Subclass Groupings).

[8] Federal Rule 3 is obviously valid, and there is no need to conduct an *Erie* analysis. *Nuveen Mun. Trust ex rel. Nuveen High Yield Mun. Bond v. Withumsmith Brown, P.C.*, 692 F.3d 283, 303 (3d Cir. 2012) (quoting *Shady Grove*, 559 U.S. at 410)).

defendants instead of in court, conflicts with Federal Rules 3 and 8.[9] Rule 3 provides that "[a] civil action *is commenced* by filing a complaint with the court[.]" (emphasis added; *see also* Advisory Committee's Note to 1937 Adoption ("[Rule 3] provides that the *first step in an action* is the filing of the complaint." (emphasis added)). Rule 8(a) specifies what the pleading should contain. The Sixth Circuit recently found (joining the Fourth Circuit), that a pre-suit notice requirement conflicted with Federal Rules of Civil Procedure 3 and 8. *Albright,* 24 F.4th at 1046-1049 ("presuit-notice requirements in diversity cases do not apply in the federal courts"). The Fourth Circuit has ruled similarly in *Pledger v. Lynch*, 5 F. 4th 511 (4th Cir. 2021), that a West Virginia statute requiring pre-suit notice "is displaced by the Federal Rules under *Shady Grove*, and therefore does not apply to Pledger's [claims in federal court]." *Id.* at 523-524.

2. Defendants Had Actual Notice of Their Economic Loss Liabilities

The point of pre-suit notice is to alert a defendant to an issue previously unknown to the defendant, so that it can be remedied. Here, each Defendant had actual knowledge of the NDMA/NDEA contamination in their VCDs without the need for any private litigant to send a notice letter. ZHP was advised by the FDA that their VCDs were "adulterated" (and therefore, as a matter of black letter law,

[9] This conflict is particularly pronounced if any state pre-suit notice requirement is considered to be incurable and a bar to recovery.

illegal to have sold pursuant to 21 U.S.C. § 331(a)). *See, e.g.*, ZHP SOMF ¶ 33-34, 52, 61-62, 73, 86, 98, 115, 126-163.2, 165, 167, 170. The FDA's public admonition of ZHP also put Teva and Torrent on notice that the API they sourced from ZHP and incorporated into their own VCDs was adulterated. *See, e.g.*, Teva SOMF ¶ 8-25, 103-108; Torrent SOMF ¶ 23-24, 24(a), 24(b), 47-48, 53.

Each Defendant then proceeded to issue recalls of ***every single pill*** within expiry[10] of their VCDs, admitting that their VCDs presented an "unacceptable carcinogenic risk" and that they should have never been sold in the first place. *See, e.g.*, ZHP SOMF ¶ 143, 155, 159; *see also, e.g., Performing Arts Ctr. Auth. v. Clark Const. Group, Inc.*, 789 So.2d 392 (Fla. App. 2001) (stating that "where there is an obvious manifestation of a defect [e.g., a recall by the defendant], notice will be inferred at the time of manifestation").

All of these events occurred before the first class lawsuit was filed in July 2018, and before the first TPP lawsuit was filed on December 14, 2018. Record evidence confirms that Defendants well-understood the issues and significant liabilities they faced from the outset. For instance, [redacted]

[10] Defendants' own testing produced in discovery further confirmed that every pill ever sold was likewise contaminated with NDMA and/or NDEA. *See, e.g.*, ZHP SOMF ¶ 143-143.5, 155, 160, 167; Teva SOMF ¶ 102; Torrent SOMF ¶ 47–49.

[redacted]. *See* Suppl. Teva SOMF ¶ 11. [redacted]. *See* Torrent SOMF ¶ 16–17. In other words, Defendants were actually putting *each other* on notice on behalf of future claimants, including but not limited to the TPP class.[11]

a. The Court Previously Held Plaintiffs Provided Pre-Suit Notice

Defendants neglect to mention that this Court already found Plaintiffs provided pre-suit notice of the express warranty claims pleaded in the original Master Complaints. *See* ECF 775, at 11-12. Under the sub-heading entitled "Pre-Suit Notice: Master Complaints for both express and implied warranty claims," the Court wrote: "the Court finds plaintiffs did provide pre-suit notice." *Id.* Defendants did not cite any intervening change in controlling law warranting revistation of this Court's prior ruling.

In so ruling, the Court cited some of same unique factual circumstances of this litigation discussed *supra* Part III.A.1.a:

[11] *Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624, 638 (Oh. 1989) (**Ohio** Supreme Court stating that "the statute [Ohio's UCC notice statute] was not meant to exclude the possibility that notice may be inferred").

> Plaintiffs also assert that, in response to and in addition to the FDA recalls in the summer and fall of 2018 and in 2019, some Mfr defendants—both API and finished dose—issued their own voluntary recalls. According to plaintiffs, such recalls indicate Mfr defendants understood that their products, already on the market, were regarded as dangerous and non-compliant with FDA standards . . . . Further, Ps assert such voluntary recalls unmistakably show the Mfr and Wholesaler defendants alike recognized that lawsuits for injury owing to the contaminated API would likely ensue and indisputably represent a conscious business strategy to reduce injury and align with the FDA. ***The Court agrees.***

ECF 775, at 11-12 (emphasis added).

b. Defendants Were Provided Notice Letters That the Court Already Determined Were Sufficient

All three Trial Defendants were served with numerous pre-suit notice letters of class economic loss claims long before the first TPP class complaint was filed in December 2018. *See* Pls.' Opp. to Defs.' SOMF ¶ 112; Teva Suppl. SOMF ¶ 110. Moreover, some of those letters gave notice of classes that expressly included "all persons," i.e., entities and individuals. *See, e.g.*, *Duffy v. Solco Healthcare U.S., LLC, et al.*, No. 1:18-cv-15076 (D.N.J.) (ECF 1, at ¶ 17); *Stimma v. Torrent Pharma, Inc., et al.*, No. 1:18-cv-14318 (D.N.J.) (ECF 1, at ¶ 29).

The notice letters sent to Defendants are more than sufficient (particularly when combined with Defendants' own recalls and knowledge,[12] *supra*) to have put

[12] *Performing Arts Center Authority v. Clark Const. Group, Inc.*, 789 So.2d 392 (Fla.App. 2001) (notice may be inferred at time of manifestation of an obvious manifestation of defect); *Hyde v. General Motors Corp*., 1982 Trade Cases ¶64,595

Defendants on notice of consumer *and* TPP express warranty claims. Given that consumers and TPPs share the costs of each prescription drug purchase, the consumer Plaintiffs' notice letters should be deemed to have placed Defendants on notice of TPP claims for their share of those purchases. Indeed, the claims are so closely related (only with a consumer transaction actually purchasing the VCDs did the TPPs' payment get triggered) that the Court ordered consumer economic loss class members and TPP class members to jointly file a single unified Economic Loss Master Complaint. And again, the Court, "[found] plaintiffs did provide pre-suit notice" sufficient to cover consumer and TPP claims. ECF 775 at 11-12 & n.5.

Finally, Defendants received pre-suit notification from at least one TPP class member. In early 2020, TPP Class Member Employers and Laborers Locals 100 and 397 Health and Welfare Fund and Steamfitters Local 439 provided putative nationwide TPP class pre-suit notice to ZHP, Teva, and Torrent. Those letters were served long before the operative Third Amended Master Economic Loss Complaint was filed on November 1, 2021. *See* Suppl. Teva. SOMF ¶ 14.

c. The Court Afforded Plaintiffs an Opportunity to Amend the Economic Loss Master Complaint to Provide Another Pre-Suit Notice Prior to Filing

The Court granted plaintiffs leave to amend the complaint to address pre-suit

(N.Y. Sup. Oct. 16, 1981) (stating that the content of any notice "merely be sufficient to let the seller know of the nature of the defect.")

requirements." ECF 775, at 12. To be thorough, Plaintiffs did just that.[13] Prior to filing the operative Third Amended Master Complaint (ECF 1708), Plaintiffs served a comprehensive pre-suit notice letter. *See* Suppl. Teva. SOMF ¶ 15.

d. The Sufficiency of Notice is a Fact Question

Even assuming *arguendo* that the Court saw an open question, whether Plaintiffs provided notice for the Express Warranty Subclass b would at worst be a fact question for the jury.[14] The facts show that Defendants were provided sufficient

[13] *Bayne v. Target Corp.*, 630 F. Supp. 3d 544, 550 (S.D.N.Y. 2022) (finding under New York law that notice can be given by filing an amended complaint and that the filing of the complaint itself is sufficient notice (citing and discussing N.Y. case).

[14] *Page v. Camper City & Mobile Home Sales*, 297 So. 2d 810, 812 (Ala. 1974) ("sufficiency of notice must be tested in light of the facts of the particular case"); *Jarrett v. Panasonic Corp. of N. Am.*, 8 F. Supp. 3d 1074, 1083 (E.D. Ark. 2013) ("Ordinarily, the sufficiency of notice is a question of fact for the jury based upon the circumstances."); *Int'l Multifoods Corp. v. Nat'l Egg Prods., Div. of Hudson Foods, Inc.*, 202 Ga. App. 263, 266 (Ga. 1991) ("The question of reasonableness of notice is ordinarily a factual one."); *Mississippi Chem. Corp. v. Dresser-Rand Co.*, 287 F.3d 359, 368 (5th Cir. 2002) (interpreting Mississippi express warranty law and finding that whether notice provision was complied with is a jury question); *Fitl v. Strek*, 690 N.W.2d 605, 608 (Neb. 2005) ("Whether the notice given is satisfactory and whether it is given within a reasonable time are generally questions of fact to be measured by all the circumstances of the case."); *Waddell v. Am. Breeders Serv., Inc.*, 505 P.2d 417, 421 (Mt. 1973); *Precourt v. Fairbank Reconstruction Corp.*, 856 F. Supp. 2d 327, 340 (D.N.H. 2012) ("Under New Hampshire law, the determination of whether defendants received sufficient notice is ordinarily a question of fact to be determined by the jury based on the surrounding circumstances."); *Hubbard v. Gen. Motors Corp.*, No. 95cv4362, 1996 WL 274018, at *4 (S.D.N.Y. May 22, 1996) (under New York law "the sufficiency and timeliness of the notice is generally a question for the jury."); *Maybank v. S. S. Kresge Co.*, 302 N.C. 129, 134, 273 S.E.2d 681, 684 (N.C. 1981); *Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E. 2d 624, 636 (Ohio 1989); *Lawson v. Palm Harbor Homes, Inc.*, No. 6:21cv212, 2022

notice. And there would have been no feasible way for Defendants to "repair"[15] the contaminated pills (which is the underlying purpose of UCC notice requirements) because they were already consumed and were recalled regardless of notice.[16]

e. <u>The Court Should Apply Principles of Equity and Estoppel</u>

All of the Express Warranty Subclass b states have enacted UCC Section 1-103, which generally states "principles of law and equity, including … estoppel … supplement its provisions."[17] Here, Defendants are estopped from arguing that pre-suit notice should have been given to them. As set forth in Plaintiffs' fraud evidence,

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WL 18025164, at *2-3 (D. Or. Dec. 30, 2022) (denying summary judgment because there were "genuine issues of material fact regarding whether [defendant] was afforded notice"); *Saber v. Dan Angelone Chevrolet*, 811 A.2d 644, 653 (R.I. 2002) (sufficiency of notice is a question of fact for jury to resolve); *Gehan Homes, Ltd. v. NIBCO Inc.*, No. 5:19-CV-1478-JKP, 2020 WL 5110707, at *8 (W.D. Tex. Aug. 31, 2020); *Ehlers v. Ben & Jerry's Homemade, Inc.*, No. 2:19cv194, 2020 WL 2218858, at *8 (D. Vt. May 7, 2020) (question of fact); *Petro-Chem, Inc. v. A.E. Staley Mfg. Co.*, 686 P.2d 589, 593 (Wyo. 1984) (adequacy of notice is question of fact for jury).

[15] *Frey v. Bayer Corp.*, 499 F. Supp. 3d 1283, 1294 (M.D. Ga. 2020) ("Frey adequately alleges that Def[s.] could not have repaired the Essure device that was implanted in her body even if she had given pre-suit notice. Thus, the Court declines to dismiss Frey's [**Ga.**] warranty claim for failure to provide pre-suit notice.").

[16] The equities weigh strongly in favor of Plaintiffs here. Had the Court previously found pre-suit notice to have been inadequate, it could have simply dismissed without prejudice. Plaintiffs could have then served pre-suit notice and re-filed. This is precisely what the Court intended by affording Plaintiffs an opportunity to cure.

[17] Ala. Code. § 7-1-103(b); Ark. Code § 4-1-103; Fla. Stat. § 671.103; O.C.G.A. § 11-1-103; Miss. Code § 75-1-103; Mont. Code Ann. § 30-1-103; Neb. Rev. Stat. U.C.C. § 1-103; NRS § 104.1103; N.H. Stat. 382-A:1-13; N.Y. Comm. Code Law § 1-103; N.C. Gen. Stat § 25-1-103; Ohio Rev. Code § 1301.103; Ore. Stat. § 71-1030; R.I. Stat. § 6A-1-103; S.C. Stat. § 36-1-103; Tex. Bus. & Comm. Code § 1.103; Utah Stat. § 70a-1a-103; Vt. Stat. § 9A-1-103; Wis. Stat. § 401.103; Wyo. Stat. § 34.1-1-103.

Defendants knew either of the contamination itself and fraudulently concealed same (or in Teva's case, of significant CGMP violations at ZHP and concealed same). It would be an inequitable result to require pre-suit notice to a defendant who was actively concealing the basis for plaintiffs' causes of action.

3. Defendants' Statute of Limitations Argument Should Be Rejected

For the first time in this litigation, Defendants raise the statute of limitations defense. The Court should reject the defense.

a. Nearly All of Defendants' VCD Sales Fall Within the Shortest Applicable Limitations Period

Alabama, Arkansas, Georgia, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, Ohio, Oregon, Rhode Island, Texas, Utah, Vermont, Wisconsin, and Wyoming have codified U.C.C. § 2-725 and adopted the 4-year statute of limitations which starts to accrue when tender of delivery is made.[18] Mississippi and South Carolina have also codified U.C.C. § 2-725 but instead enacted a 6-year statute of limitations.[19] Florida has not codified U.C.C. §2-725 and

[18] Alabama (Ala. Code §7-2-725); Arkansas (Ark. Code Ann. § 4-2-725); Georgia (O.C.G.A § 11-2-725); Montana (Mont. Code Ann. 30-2-725); Nebraska (R.R.S. Neb.(UCC) § 2-725); Nevada (Nev. Rev. Stat. Ann. 104.2725); New Hampshire (RSA § 382-A:2-725); New York (NY UCC § 2-725); North Carolina (N. C. Gen. Stat. §25-2-275); Ohio (ORC Ann.§1302.98); Oregon (ORS §72-7250); Rhode Island (R. I. Gen. Laws §6A-2-275); Texas (Tex. Bus.& Com .Code §2.725); Utah (Utah Code Ann. §70A-2-275); Vermont (9A V.S.A.§2-725); Wisconsin (Wis. Stat. §402.725) and Wyoming (Wyo. Stat. §34.1-2-725). See ECF 2562-1, p. 11 – Defendants agree SOL period runs from point of sale.

[19] Miss. Code Ann. §75-2-725; S.C. Code Ann. §36-2-275.

has a 5-year statute of limitations deeming breach occur only once the defect is discovered or should have been discovered.[20]

First, nationwide class actions (including some that sought to represent "all persons," i.e., entities and individuals) were filed in July, August, and September of 2018, *see supra*. In addition, TPP Class Representative MSP Recovery Claims, Series LLC ("MSP") filed a class action complaint seeking to represent a nationwide class of TPPs (and consumers) against ZHP and Teva on December 14, 2018. *See* 1:19-cv-06830 (D.N.J.) at ECF 1. Soon after, the Maine Automobile Dealers Association Inc. Insurance Trust ("MADA") filed a class action complaint seeking to represent a nationwide class of TPPs against ZHP, Teva, Torrent, and others on January 30, 2019. *See* No. 1:19-cv-02431 (D.N.J.), at ECF 1. The Consolidated Amended Economic Loss Class Action complaint naming all of the previously listed defendants was filed on June 17, 2019. *See* ECF 121.

ZHP sold contaminated VCDs via its wholly owned subsidiaries, Prinston and Solco, in the United States beginning on October 2, 2015, through recall in July 2018. *See* ZHP SOMF ¶ 24. Torrent VCDs were sold in the United States beginning in January 2015 through recall in July 2018. *See* Torrent SOMF at ¶ 5. Actavis/Teva's VCDs were sold in the United States starting on or about March 21,

[20] Fla. Stat. Ann. §95.11(2)(b); *McKissic v. Country Coach, Inc.*, 2009 WL 500502; 2009 U.S. Dist. LEXIS 16478 (M.D. Fla. 2009) at *24-26.

2013, through recall in July 2018. *See* Teva SOMF at ¶ 1.

Even using the tightest possible statute of limitations (four years), and assuming MSP's filing in December 2018 is the trigger date, nearly all of Defendants' VCD sales occurred within the narrowest limitations period (i.e., four years prior from December 14, 2018 is December 14, 2014). That date moves back with the prior filed complaints in July and August 2018.

b. Application of the Discovery Rule

Here, Defendants themselves have filed Answers containing affirmative defenses that not even *they* could have known of the contamination at any point prior to recall. *See* ECF 2547, 2548, 2549, at 64. While these defenses are meritless, Defendants are nevertheless estopped from claiming that the TPP Class Members could have reasonably known, and therefore should have filed suit sooner than the recall dates in July 2018 (from which any applicable statute of limitations would begin to run).[21] Contrary to the defendants' assertions, Nevada and South Carolina in addition to Florida have a discovery rule for warranty claims which makes any claim for contaminated VCDs timely as the third-party payors only became aware

[21] See **Florida** - *McKissick v. County Coach, Inc*, 2009 WL 500502, 2009 U.S. Dist. LEXIS 16478 at *32-33 (M.D. Fla. 2009); **Nevada** - (*Herrera v. Toyota Motor Sales, U.S.A.*, 2010 WL 3385336, 2010 U.S. Dist. LEXIS 95399 at *4 (D. Nev. 2010); and **South Carolina** - *Harrell v. BMW of N. Am., LLC*, 2021 WL 409836, 2021 U.S. Dist. LEXIS 22343 at **6 (D. So.C. 2021).

of contamination when the recalls were announced.[22] At a minimum, the discovery rule's application is a fact question for the jury. *See, e.g.*, *Mest v. Cabot Corp.*, 449 F.3d 502, 510-515 (3d Cir. 2006).

c. Fraudulent Concealment/Equitable Estoppel

Alabama, Arkansas, Florida, Georgia, Mississippi, Montana, Nebraska, New York, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin, and Wyoming all recognize fraudulent concealment and/or equitable estoppel doctrines which toll the running of the statute of limitations.[23] In

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[22] See **Florida** - *McKissick v. County Coach, Inc*, 2009 WL 500502, 2009 U.S. Dist. LEXIS 16478 at *32-33 (M.D. Fla. 2009); **Nevada** - (*Herrera v. Toyota Motor Sales, U.S.A.*, 2010 WL 3385336, 2010 U.S. Dist. LEXIS 95399 at *4 (D. Nev. 2010); and **South Carolina** - *Harrell v. BMW of N. Am., LLC*, 2021 WL 409836, 2021 U.S. Dist. LEXIS 22343 at *6 (D. So.C. 2021).

[23] **Alabama** - *Selby v. Goodman Mfg. Co. LP*, 2014 WL 2740317; 2014 U.S. Dist. LEXIS 82182 (D. Ala., So. Div. 2014); **Arkansas** - *J & B Tankers, Inc. v. Navistar Int'l Corp*., 539 F. Supp. 3d 955 (E.D. Ark. 2021) at *961-962, *B & B Hardware, Inc. v. Fastenal Co*., 688 F. 3d 917, 921 (8th Cir. 2012); **Florida** - *First Fed. Sav. & Loan Ass'n. v Dade Fed.Sav. & Loan Ass'n*., 403 So. 2d 1097, 1101 (Dist. Ct. of App., Fifth Dist. 1981); **Georgia** - *McElmurray v. August-Richmond County*, 274 Ga. App. 605 (Ct. of App. 2005) at 614-615; **Mississippi** - *Neyland v. Timberland Mgmt. Serv*., 167 So. 3d 1272 (Ct. of Appeals of Miss. 2014), *Miss. Code Ann. 15-1-67;* **Montana** - *In re ZF-TRW Airbag Control Units Prods. Liab. Litig*., 601 F. Supp. 3d 625, 828-829 (Cal. Central D.C. 2022), *Yellowstone Conference of United Methodist Church v. D.A. Davidson, Inc*., 228 Mont. 288,294; 741 P.2d 794 (Sup. Ct. Mont. 1987), *Mont. Code Ann. § 27-2-102(3);* **Nebraska** - *In re Saturn L-Series Timing Chain Prods. Liab. Litig*., 2008 WL 4866604; 2008 U.S. Dist. LEXIS 109978 (D.C. Neb. 2008) at *17-21; **New York** - *United States v. Pall Corp*., 367 F. Supp. 976, 979 (E.D.N.Y. 1973); **North Carolina** - *Jones v. BMW of N. Am. LLC,* 2020 WL 5752808; 2020 U.S. Dist. LEXIS 176568 (M.D. No. Car. 2020) at *10-11; **Ohio** - *Axios, Inc. v. Thinkware, Inc*., 2015 US Dist. LEXIS 113167 (O.S.D.C.

general, "[t]he doctrine of fraudulent concealment estops a defendant from asserting a statute of limitations defense when the defendant has, **either by deception or by violation of a duty**, concealed from plaintiff material facts which prevent the plaintiff from discovering the (act or conduct)." *See In re Saturn L-Series Timing Chain Prods. Liab. Litig*., 2008 WL 4866604; 2008 U.S. Dist. LEXIS 109978, at *20-21.

All Defendants violated their duties to promptly identify and disclose the contamination throughout the lifecycle of the drugs—aside from their duty never to sell them in the first place. And there is clear evidence that ZHP's sale of valsartan API and finished dose constituted knowing fraud beginning at least as early as July 27, 2017, and that Torrent's sale of finished dose valsartan-containing drugs from August 3, 2018, through August 17, 2018, constituted knowing fraud. *See* ZHP SOMF ¶ 40-42; Torrent SOMF ¶ 15, 21, 53. Similarly, Torrent and Teva had strong

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2015) at *15-17, *Jones v. Lubrizol Advanced Materials,* 559 F. Supp. 3d 569, 606 (O.N.D.C. 2021); **Oregon** - *Roberson Motors, Inc. v. Cooper Lighting, LLC*, 641 F. Supp. 3d 945 (D.C.O. 2022); **Rhode Island** - *R.I. Gen Laws Section 9-1-20* which codifies accrual of concealed cause of action. See, *Blouin v. Surgical Sense, Inc,* 2008 R.I. Super. LEXIS 63 (Superior Ct. R.I., Providence 2008) at *9-13; **South Carolina** - *Harrell v. BMW of N. Am., LLC*, 517 F. Supp. 3d 527, 537 (D. S.C., Columbia Div. 2021); **Texas** - *BP Am. Prod.Co. v. Marshall*, 342 S.W.3d 59, 65-66 (Sup. Ct. Tx. 2011), *Hooks v. Samson Lone Star, Ltd. P'Ship*, 457 S.W.3d 52, 57 (Sup. Ct. Tx. 2015); **Utah** - *Castle v. Thor Motor Coach, Inc*. 2019 US Dist. LEXIS 16597 (D. Utah 2019), at *7-10; **Vermont** - *Aube v. O'Brien*, 140 VT 1 (Sup. Ct. Vt. 1981), at 4-5; **Wisconsin** - *Haley v. Kolbe & Kolbe Millwork Co.,* 2015 US Dist. LEXIS 77542 (W.D.C. Wi. 2015) at *32-35; **Wyoming** - *Turner v. Turner*, 582 P.2d 600, 602-603 (Sup. Ct. Wyo. 1978).

reason to suspect their VCDs contained NDMA and/or NDEA by June 20, 2018, if not before, *see* Torrent SOMF ¶ 50(a); Nigh Cert., Ex. 6, at 183:8–24 (route of synthesis); Torrent SOMF, ¶ 9 (date ZHP notified Torrent of contamination of API),; Teva SOMF ¶ 74 (same), if not before. For example, [redacted]. (Teva SOMF, ¶ 66-67.) Throughout, Defendants misrepresented that their API or VCDs were as approved.

d. <u>The Statute of Limitations is Tolled By Operation of the Continuous Violation Doctrine</u>

"Certain wrongs are considered to be continuing wrongs, and the statute of limitations, therefore, runs from the commission of the last wrongful act." *Leonhard v. United States*, 633 F.2d 599, 613 (2d Cir. 1980) (internal quotation marks and citation omitted). Continuous violations are found to exist if: "(1) the defendants engage in continuing wrongful conduct; (2) injury to the plaintiffs accrues continuously; and (3) had the defendants at any time ceased their wrongful conduct, further injury would have been avoided." *Cnty. of Summit v. Purdue Pharma L.P. (In re Nat'l Prescription Opiate Litig.)*, MDL No. 2804, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018). Under the doctrine, "when a defendant's conduct is part of a continuing practice, an action is timely so long as the last act evidencing the continuing practice falls within the limitations period." *Cowell v. Palmer Twp.,* 263 F.3d 286, 292 (3d Cir. 2001). The doctrine applies in the pharmaceutical drug context where, for instance, a manufacturer fails to warn of a

risk through the time the risk is revealed (*see, e.g.*, *Haddad v. Merck*, No. 22-cv-2151, 2022 WL18397392, at *5-6 (C.D. Cal. Dec. 9, 2022)), or in an economic damages context where a drug is repeatedly sold at an artificially inflated price (*see, e.g.*, *In re Niaspan Antitrust Litigation*, 42 F. Supp 3d 735, 746-47 (E.D. Pa. 2014)).

Defendants engaged in continuing wrongful conduct, and had Defendants withdrawn the false warranties and/or stopped selling the contaminated VCDs further damages would have been avoided. The last act of Defendants' continuing practices (i.e., the last sale of each VCD) occurred well within the applicable limitations periods (i.e., July 2018). *See* ZHP SOMF at ¶ 24; Torrent SOMF at ¶5; Teva SOMF at, ¶ 1.

4. Defendants' Express Warranties Exist, Were Breached, and Were Relied On.

Defendants correctly note that this Court has already ruled in favor of Plaintiffs on express warranty:

> **[F]or prescription drugs, the mere identifying and marketing a drug as THE generic equivalent to a branded pharmaceutical listed in the Orange Book and then selling that generic equivalent when it contains a contaminant not included in the Orange Book listing constitutes a breach of express warranty. . . .**
>
> The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for their high blood pressure. **Plaintiffs did not have to "perceive" the package labelling or insert in order to create a benefit of the bargain. All they had to know was they were buying a generic drug that contained valsartan because the very name**

> **"valsartan" or "valsartan-containing" constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical**.

In re Valsartan, Losartan, Irbesartan Prods. Liab. Litig., MDL No. 2875 (RBK-JS), 2021 WL 222776, at *11 (D.N.J. Jan. 22, 2021) (emphasis added) (ECF 775).

Defendants cannot escape this fundamental ruling. Defendants' first argument to this end focuses on the deposition testimony of Summacare's and Emblem's representatives (*Id.*). First, the questions asked in the cited testimony failed to address the facts in a thorough or directly relevant way—key representations were made and were relied on by the TPPs. (Pls. Opp. to Defs,' SOMF ¶ 84-85, 108, 119; MSP Ex. 17 ([redacted]). Liability here does not rest on Summacare's, Emblem's, or any other class members' "hav[ing] to 'perceive' the package labelling or insert," because the representations at issue (FDA approval, DMF and ANDA compliance, USP compliance, and AB rating in the Orange Book) are required in order to permit the sale of the VCDs at every step of the stream of economic transactions at issue.

Valsartan, 2021 WL 222776, at *11. (Pls. Opp. to Defs,' SOMF ¶ 83-86, 88, 92-93); *Mylan Labs Ltd. v. U.S. Food & Drug Admin.*, 910 F.Supp.2d 299, 301 (D.D.C. 2012) (specifically discussing the USP monograph for valsartan, holding "if a USP monograph exists for an approved drug, an ANDA referencing that drug must meet the standards set forth in the monograph to gain FDA approval"); *U.S. v. Lanpar Co.*, 293 F.Supp. 147, 153-54 (N.D. Tx. 1968) (citing 21 U.S.C. § 351, 352). This is completely in line with Dr. Panagos' exposition of the Orange Book, which the Court did not preclude at class certification (ECF 2261, at 93-94) or more recently (ECF 2581, at 22-23). For example:

1. TPPs and P&T Committees expressly rely upon the manufacturers' compliance with all applicable standards, obligations, and regulations. (Pls.' Opp. to Defs,' SOMF ¶ 119).

2. It is industry practice that a drug must be safe in order to gain approval by the FDA and a listing in the Orange Book is an important source which by design is relied on throughout the pharmaceutical industry. (*Id.*).

3. TPPs, PBMs, and P&T Committees rely on the FDA approval as the indicator that the medication may be considered for formulary placement and plan coverage/reimbursement. (*Id.*).

4. The pharmaceutical industry, including TPPs, are meant to be able, by design, to rely on the information in the Orange Book such that these FDA approved generics can be put on a prescription drug formulary and/or plan coverage for reimbursement. (*Id.*).

5. P&T committees and TPPs rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan. (*Id.*).

The Court was clear that "whether [the Orange Book's] TE codes and subcodes constitute a warranty is a legal question," meaning a question for the Court, which has already ruled on this issue. (ECF 2261, at 94).

Additionally, Dr. Rena Conti's opinions establish that TPPs relied on Defendants' compliance with applicable standards, obligations, and regulations in determining which drugs to reimburse:

> If a prescription drug is available for sale in the United States, patients and third-party payers rely on the manufacturer's assurance that the drug has the safety, identity, purity, potency, and quality it purports to have, as required by law and applicable regulations.
>
> * * *
>
> The assurance of safety and quality by the manufacturers of prescription drugs is foundational to third-party payers' decision making. In other words, in the United States prescription drug market, insurers do not monitor drug manufacturers' compliance with laws and regulations related to safety and quality; that is not their job. Instead, they presume that drug manufacturers are in compliance with all applicable laws and regulations related to safety and quality, that the drugs are not adulterated or misbranded ….There is no insurer demand for non-safety and quality compliant, adulterated, and misbranded drugs.

(Pls.' Opp. to Defs,' SOMF ¶ 119).

Defendants' inexplicable position that "the levels of all impurities in the VCDs at issue were within the specification limits approved by the FDA, and the VCDs remained pharmaceutically equivalent and bioequivalent to the RLDs," is easily rejected. (Defs.' Omnibus Mot., at 17). The argument that the failure to list NDMA or NDEA as impurities in the DMF and/or ANDAs permitted Defendants to

include these probable human carcinogens in their VCDs is absurd. If correct, no unlisted poison or carcinogen would violate the specifications—that is obviously wrong as a matter of law.[24] **The USP makes this very clear—a change in manufacturing process as occurred here required the use of whatever means were necessary to identify and address any impurities that resulted**. (*See* Pls.' Opp. to Defs,' SOMF ¶ 68, 70, 72-73, 76, 93, 118). Not only was this the clear USP requirement, the FDA also clearly stated that the manufacturer is responsible for the quality of its drugs, and must do what is necessary to identify and address all impurities, in particular genotoxic probable human carcinogens. (*Id.* at ¶ 61, 67). And the Defendants agree. (*See* Pls.' Opp. to Defs,' SOMF ¶ 67).

Defendants were required to recall the contaminated drugs and cease using the offending manufacturing processes because of the contamination. The record is undisputed that Defendants had an obligation to identify and report the existence of NDMA and NDEA in their VCDs and stop selling the pills. (*See* Pls.' Opp. to Defs.' SOMF ¶ 86-94).

Defendants also argue that "Plaintiffs' express warranty claims also fail for lack of reliance." (Defs.' Omnibus Mot., at 17). The Court has already held that

[24] One could easily see the absurd result. Imagine a drug contaminated with a poison *guaranteed to kill* anyone who ingested it, but the poison was not listed in the specification and the amount (while still causing death 100% of the time) was less than the 0.1% for any other impurity. Yet Defendants in this litigation claim that sale of such a poisoned drug would be appropriate.

"Plaintiffs [including TPP class members] did not have to 'perceive' the package labelling or insert in order to create a benefit of the bargain." *Valsartan*, 2021 WL 222776, at *11 (emphasis added). This holding accounts for the reality of the drug supply chain, and is reasonable because Plaintiffs' express warranty claims concern warranties necessary to permit the sale of the VCDs. No one asserts that the drugs would have been available for sale and willingly purchased by anybody if the contamination was disclosed. As ZHP admitted, [redacted] [redacted] (*See* ZHP SOMF ¶ 157). If Defendants had not warranted the VCDs were FDA approved, USP compliant, and AB rated in the Orange Book, meaning that they were represented to be therapeutically equivalent to the RLDs with regard to quality and purity among other things, then the sale of the VCDs would have been prohibited at each step of the economic transactions at issue.

Plaintiffs also note that Paragraph 122 of Defendants' Statement of Facts concedes that both assignors had P&T Committees, and "P&T committees rely on a wide range of documents and sources to develop formularies[,] include[ing] medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, provider recommendations, **FDA-approved package inserts, the product label**, published data from clinical trials, and relevant patient experiences." (emphasis added). This further establishes Plaintiffs' reliance—to the extent necessary. (Pls. Opp. to Defs.' SOMF ¶ 84-94, 108, 119).

Finally, there is the factual reality of every transaction in which the TPPs paid for VCDs. Each was initiated by an insured patient who also relied on the representation that they were purchasing the FDA approved valsartan.[25] (Pls.' Opp. to Defs.' SOMF ¶ 117, 119). Thus, not only does the record here show that the TPPs were relying on the manufacturers' warranties in representing that their drugs were FDA approved valsartan to authorize the payments, they were also derivatively relying on and benefitting from their insured's choice to purchase the drugs based on the representation that they were obtaining FDA approved valsartan.

B. Implied Warranty Claims

Plaintiffs acknowledge that the states of Implied Warranty Subclass Group d require privity of contract without any applicable exception that would cover TPPs' relationship with Defendants. Accordingly, the Court need not reach the issue of whether Defendants' VCDs were merchantable (which can be reserved for a later trial on a different implied warranty subclass).[26]

[25] The retailers have also confirmed that they only sold the valsartan because it was represented to be the FDA approved formulation, not the adulterated drugs that they were selling. (*See* ZHP SOMF ¶ 144).

[26] Defendants' arguments on the merchantability are entirely wrong and ignore the Court's prior ruling (Mot., at 15 (citing and quoting ECF 775, at 20)), and this Court's rejection of the opinion that drugs are only adulterated prospectively, calling it illogical "sophistry" on the part of Defendant Teva's expert Roger Williams and precluding him from offering it. (ECF 2581, at 16-17.)

C. Defendants Mischaracterize Plaintiffs' Common Law Fraud Claim

1. Plaintiffs' Fraud Claims Are Premised on Defendants' Knowing Sale of VCDs Contaminated with NDMA and/or NDEA, and Made in a Non-cGMP Compliant Manner

This Court has correctly observed that the "basic elements" of common law fraud are "virtually the same" across all jurisdictions. (ECF 818, at 12.) As relevant to this common law fraud Subclass c (jurisdictions where the scienter standard is highest), those elements of common-law fraud are: (1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages.[27]

[27] *Cornelison v. TIG Ins.*, 376 P.3d 1255, 1270 (Alaska 2016); *Muccio v. Hunt*, 490 S.W.3d 310, 312–13 (Ark. 2016); *Bristol Bay Prods., LLC v. Lampack*, 312 P.3d 1155, 1160 (Colo. 2013); *Saucier v. Countrywide Home Loans*, 64 A.3d 428, 438–39 (D.C. 2013); *Townsend v. Morton*, 36 So. 3d 865, 868 (Fla. Dist. Ct. App. 2010); *Frontier Dev. Grp., LLC v. Caravella*, 338 P.3d 1193, 1198 (Idaho 2014); *Wilden Clinic, Inc. v. City of Des Moines*, 229 N.W.2d 286, 292 (Iowa 1975); *Albe v. City of New Orleans*, 2014-0186 (La. App. 4 Cir. 9/17/14), 150 So. 3d 361, 368, n.8, writ denied, 2014-2166 (La. 12/8/14), 153 So. 3d 445; *Balles v. Babcock Power Inc.*, 70 N.E.3d 905, 913 (Mass. 2017); *U.S. Bank N.A. v. Cold Spring Granite Co.*, 802 N.W.2d 363, 373 (Minn. 2011); *Allstate New Jersey Ins. Co. v. Lajara*, 117 A.3d 1221, 1231 (N.J. 2015); *Morrow v. MetLife Invs. Ins. Co.*, 113 N.Y.S. 3d 421, 423 (N.Y. 2019); *Terry v. Terry*, 273 S.E.2d 674, 677 (N.C. 1981); *Diemert v. Johnson*, 299 N.W.2d 546, 548 (N.D. 1980); *Siegel v. Ringer*, 94 N.E.3d 1178, 1185 (Ohio 2017); *Bowman v. Presley*, 212 P.3d 1210, 1218 (Okla. 2009); *Parker v. Byrne*, 996 A.2d 627, 634 (R.I. 2010); *Johnson v. Miller*, 818 N.W.2d 804, 814 (S.D. 2012); *Estate of Alden v. Dee*, 35 A.3d 950 (Vt. 2011); *State Farm Mut. Auto. Ins. Co. v. Remley*, 618 S.E.2d 316, 321 (Va. 2005); *Adams v. King Cty.*,192 P. 3d 891, 902 (Wash. 2008); *Birt v. Wells Fargo Home Mortg., Inc.*, 75 P.3d 640, 656 (Wyo. 2003); *Microsoft Corp. v. Computer Warehouse*, 83 F. Supp. 2d 256, 262 (D.P.R. 2000).

Plaintiffs' common law fraud claims against ZHP and Torrent are premised on their knowing sale of contaminated and adulterated VCDs, addressed in Plaintiffs' affirmative ZHP- and Torrent-specifc Summary Judgment Motions and accompanying statements of fact, and separate briefs in opposition to the Defendants' motions specific to each. Teva, likewise, knowingly misrepresented that its VCDs contained API made in a cGMP compliant manner and were as FDA approved. *See* Pls.' Opp. to Teva Mot. (filed contemporaneously herewith).

Defendants shy away from the crushing facts and incredibly argue that "there is no evidence that the presence of nitrosamines affected the therapeutic equivalence of the VCDs," (*see* Defs.' Omnibus Mot., at 20). Moreover, Plaintiffs' fraud claims do not rise or fall on the lack of therapeutic equivalence (even though that is certainly one basis). And there is overwhelming evidence that they were not. This includes admissions by Defendants' corporate representatives that therapeutic equivalence requires the drug to meet the quality and purity specifications of the FDA approval. (*See* ZHP SOMF ¶ 147; *see also* Hai Wang 3/10/21 Dep. Tr., 52:2-84:19 (ZHP Ex. 2); Torrent SOMF ¶ 57). The FDA's Orange Book Preface states that to be considered a therapeutic equivalent, a drug must, among other things, (1) be pharmaceutically equivalent by meeting compendial standards, and (2) be

manufacturered in compliance with CGMPs.[28] In addition, there are the significant CGMP violations (many of which were documented by the FDA) that led to Defendants' failure to prevent and/or detect the contamination of their VCDs with NDMA and/or NDEA. (*See* Pls.' Opp. to Defs.' SOMF ¶ 61; ECF 2581).

Moreover, Plaintiffs' experts also confirm that Defendants' NDMA- and/or NDEA-contaminated VCDs did not meet USP specifications, respectively. (ECF 2581), while the Court correctly excluded all of Defendants' experts who opined that their contaminated VCDs remained therapeutically equivalent. (ECF 2581 at 6 (precluding Afnan), 10 (precluding Baertschi from opining that Teva's VCDs were the "same" as RLD), 11 (precluding Bottorff), 17 (precluding Williams)).

Finally, Defendants' citation to and description of the *United States v. Vepuri* case is entirely misleading. Defs. Omnibus Mot. at 20. The *Vepuri* case had nothing to do with impurities; the word appears not once in the decision. 74 F. 4th 141 (3d Cir. 2023). Rather, the case involved sourcing API from an undisclosed source and the record showed that the composition of the API was exactly as approved. *Id.* at 150 ("the Hydroxyzine at issue has the same composition").

[28] *See also* 21 CFR 314.3(b) (defining therapeutic equivalents as, aside from being pharmaceutically equivalent and bioequivalent, as having the "same clinical effect **and safety profile** when administered to patients") (emphasis added).

2. *As with Warranty Claims, TPP Class Members Had No Choice But to, and Did in Fact, Rely on Defendants' False Representations*

Defendants also argue that there is not enough evidence to make a triable issue for TPP Class Members' reliance on Defendants' false representations in their VCDs labeling. Defs.' Omnibus Mot., at 20-22. Quite to the contrary, TPP class members' reliance is exactly as the Court has already found: unavoidable. *See* ECF 775, at 14 (finding that consumer and TPP plaintiffs "had no choice but to 'rely'" on Defendants' labeling representations.)

Defendants contort the nature of the claim and proof, asserting that Plaintiffs have no evidence of any adverse formulary actions taken against the drugs and cite the entirely distinguishable *Testosterone ("TRT")* litigation. (Mot., at 21-22.) Here, no formulary action by TPPs was ever needed to ensure TPPs stopped reimbursing for Defendants' at issue VCDs. That is because all of Defendants' drugs were *recalled* and removed from the market. In addition, [redacted] (Pls. Opp. to Defs. SOMF ¶ 108, 119, 122, 124).

D. Defendants' Legal Challenges to Plaintiffs' Consumer Protection Law Claims Are Legally Meritless

Defendants assert that Plaintiffs cannot prove deceptive conduct. Notably, Defendants do not argue that they are entitled to summary judgment on the "unfair"

prongs of these statutes.

1. Plaintiffs' Can Easily Prove That Defendants Engaged in "Deception" Under CPL Subclass A Laws

Defendants suggest that some level of scienter is required. Not so. CPL Subclass A consists of states where no showing of intent is required to prove deception.[29] Defendants' cited cases are all inapposite. The *In re Epipen* decision from the District of Kansas was a class certification decision. This Court has certified Plaintiffs' groupings of CPL claims, and class certification is not at issue here. The quotations from both the *In re Temporomandibular Joint (TMJ) Implants Products*

[29] *See Borgen v. A&M Motors, Inc.*, 273 P.3d 575, 591 (Alaska 2012); *State ex rel. Babbit v. Goodyear Tire & Rubber Co.*, 626 P.2d 1115, 1118 (Ariz. Ct. App.1981); *Prakashpalan v. Engstrom, Lipscomb & Lack*, 223 Cal. App. 4th 1105, 1133 (Cal. App. 2nd Dist. 2014); *Lawrence v. Richman Group Capital Corp.*, 358 F. Supp. 2d 29 (D. Conn. 2005); *PNR, Inc. v. Beacon Prop. Mgmt., Inc.*, 842 So.2d 773, 777 (Fla. 2003); *Morice v. Hosp. Serv. Dist. #3*, 430 F. Supp. 3d 182, 216 (E.D. La. 2019) (A misrepresentation is "deceptive" for purposes of LUTPA); *Duncan v. Savannah, LLC*, 637 S.W.3d 633, 643 (Mo. Ct. App. 2021) ("It is the defendant's conduct, not his intent, which determines whether a violation has occurred." (citations and quotations omitted)); *Raad v. Wal-Mart Stores, Inc.*, 13 F. Supp. 2d 1003, 1014 (D. Neb. 1998) ("practice possessed the tendency or capacity to mislead"); ECF 2261, App'x I, at 20 (this Court stating, with respect to New Hampshire law, that the "P[laintiffs] could claim violation under several enumerated prohibitions by D[efendant]s in the statute that do not require scienter."); *Pension Fund v. Marine Bank*, 85 N.Y.2d 20, 26 (N.Y. 1995); *Myers v. Liberty Lincoln-Mercury, Inc.*, 365 S.E.2d 663, 664 (N.C. 1988) ("purchaser of misrepresented merchandise does not have to prove fraud, bad faith or intentional deception"); *DJ Coleman, Inc. v. Nufarm Americas, Inc.*, 693 F. Supp. 2d 1055 (D.N.D. 2010); *Trotter v. Am. Mod. Select Ins. Co.*, 220 F. Supp. 3d 1266, 1269 (W.D. Okla. 2016); *State ex rel. Rosenblum v. Johnson & Johnson*, 362 P.3d 1197, 1203 (2015); *Gregg v. Ameriprise Fin., Inc.*, 245 A.3d 637, 650 (Pa. 2021); *State v. A.N.W. Seed Corp.* 802 P.2d 1353 (Wash. 1991).

Liability and the *E.R. Squibb & Sons, Inc. v. Stickney* case involved common law fraud claims, not CPL claims, and are therefore inapplicable. Finally, the *Parker v. United Industries Corporation* court found there was no evidence that the mosquito repellent label contained any false statement. No. 17cv5353, 2020 WL 5817012 (S.D.N.Y. Sept. 29, 2020). The court did not rule or in any way suggest that any level of intent is required under New York's CPL. *Pension Fund v. Marine Bank*, 85 N.Y.2d 20, 26 (N.Y. Ct. App. 1995) ("[I]t is not necessary under the statute that a plaintiff establish the defendant's intent to defraud or mislead[.]"). Here, by contrast, Defendants will be "hard pressed to refute" (ECF 2261, at 21) that they made false written representations.

Second, Defendants' conduct constituted "deception" under the CPL Subclass A laws. All of the CPL Subclass A states have standardized violation language (generally prohibiting "deceptive" or "unfair" practices[30]), which language encompasses the ZHP, Teva, and Torrent Defendants' respective conduct. Indeed, the vast majority of the CPL Subclass A states explicitly instruct courts to incorporate guidance and decisional law made pursuant to the Federal Trade Commission Act ("FTC Act") as determinative in construing their own CPL laws (Alaska, Arizona, California, Connecticut, Florida, Hawaii, Louisiana, New York,

[30] Again, Defendants do not move for summary judgment on the "unfair" prong of these statutes.

New Hampshire, North Carolina, Washington).[31]

The Third Circuit has emphasized the FTC's ability to "deem a practice unfair [or deceptive]" under the FTC Act via its issuance of policy statements. *F.T.C. v. Wyndham Worldwide Corp.*, 799 F.3d 236 (3d Cir. 2015). To establish "deception" under the FTC Act, (1) there must be a representation, (2) the representation was likely to mislead customer acting reasonably under the circumstances, and (3) the representation must be material. *F.T.C. v. Millennium Telecard, Inc.*, No. 11cv2479, 2011 WL 2745963, at *3 (D.N.J. July 12, 2011) (Linares, J.) (citing authorities). The FTC has issued policy statements on deception that unambiguously cover the circumstances of this case. In its 1983 Policy Statement on Deception, the FTC stated that: "Practices that have been found misleading or deceptive in specific cases include false oral or written representations … **sales of hazardous or systematically**

[31] *Borgen v. A & M Motors, Inc.*, 273 P.3d 575, 583 (Alaska 2012); Arizona Rev. Stat. § 44- 1522(C); *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 543 (Cal. 1999); Conn. Gen. Stat. Ann. § 42-110b; Fla. Stat. Ann. § 501.204; Haw. Rev. Stat. Ann. § 480-2; *Cheramie Servs., Inc. v. Shell Deepwater Prod., Inc.*, 2009-1633 (La. 4/23/10), 35 So. 3d 1053, 1056 ("this 1972 [Louisiana] legislation was modeled after the [FTC Act]"); *F.T.C. v. Crescent Pub. Grp., Inc.*, 129 F. Supp. 2d 311, 318 (S.D.N.Y. 2001) ("Moreover, the [New York] state law is modeled in part on the FTCA and compliance with the FTCA is a defense to charges under the law."); N.H. Rev. Stat.Ann. § 358- A:13; *Johnson v. Phoenix Mut. Life Ins. Co.*, 266 S.E.2d 610, 620 (N.C. 1980) ("[I]t is appropriate for us to look to the federal decisions interpreting the FTC Act for guidance" in construing N.C. Gen. Stat. § 75-1.1); *State v. Living Essentials, LLC*, 436 P.3d 857, 866 (2019) ("Washington courts have repeatedly adopted federal court interpretations of section 5 of the FTCA when reviewing CPA cases.").

defective products [] without adequate disclosures … and **failure to meet warranty obligations**." (Oct. 14, 1983 FTC Policy Statement on Deception ("the FTC Deception Policy Statement (emphasis added) (ZHP Ex. 124)). That happened here as a matter of law. When the contamination was disclosed the Trial Defendants recalled their VCDs, admitted they were all contaminated with probable human carcinogens NDMA/NDEA, and even stated publicly that their VCDs represented an "unacceptable carcinogenic risk." (*See, e.g.,* ZHP SOMF ¶ 155.)

For those states that do not expressly look to FTC Act guidance (Missouri,[32] Nebraska,[33] Oklahoma,[34] Oregon,[35] Pennsylvania[36]), the very same result is reached

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[32] Missouri's CPL "broadly" prohibits "deception" and deliberately has not defined that term to promote the remedial purposes of the statute. *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 759 (W.D. Mo. 2015) (citing and quoting cases).

[33] Nebraska defines deception possessing the tendency to mislead, without regard to any materiality requirement. *Raad v. Wal-Mart Stores, Inc.*, 13 F. Supp. 2d 1003, 1018 (D. Neb. 1998).

[34] Oklahoma's CPL prohibits both unfair and deceptive practices, and defines "deceptive" as "a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person." Okla. Stat. tit. 15, §§ 753, 752(13), (14).

[35] Oregon's "unconscionability" standard includes deception as this Court has previously found. (ECF 2261, App'x I, at 26 (citing and quoting *State ex rel. Rosenblum v. Johnson & Johnson*, 62 P.3d 1197 (Ore. Ct. App. 2015), *aff'd* 358 Or. 611 (Ore. 2016) ("A material risk that a product has a latent defect is exactly the kind of inherent feature of a product implicated under ORS 646.608(1) and (2).").)

[36] Pennsylvania's enumerated deceptive practices include TPP Trial Defendants' conduct, *inter alia*, "representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another[;]" "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have[;]"

based on the same evidence and same analysis. (*See* Pls.' Omnbius Mot. for SJ, at 26-38.)

2. TPPs Have Standing to Sue in All of the CPL Subclass A States

Defendants assert that TPPs lack standing to sue in the District of Columbia, Hawaii, Missouri, Montana, and Ohio.[37] First, the District of Columbia, Montana, and Ohio are not part of CPL Subclass A and the Court need not decide this issue for those jurisdictions. (ECF 2532-6 (TPP subclasses submitted for class notice approval) & ECF 2535 (order approving same).)

Under Hawaii law, a business has standing to sue under the "unfair competition" prong of its statute. *See* Haw. Rev. Stat. § 480-2. The only added element would be harm to competition generally, evidence of which Plaintiffs intend to submit at trial on account of the Defendants flooding of the pharmaceutical supply chain with their adulterated and contaminated VCDs (to the point that the recall actually caused a shortage of non-contaminated VCDs). *See e.g., BlueEarth*

"[c]ausing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services[;]" or "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding[.]" Pa. Cons. Stat. § 201-1, 201-2, & 201-3; *see also Gregory v. Metro Auto Sales, Inc.,* 158 F.Supp.3d 302 (E.D. Pa. 2016) (Under Pennsylvania law, courts should liberally construe the Unfair Trade Practices and Consumer Protection Law (UTPCPL) in order to effect the legislative goal of consumer protection).

[37] Plaintiffs' affirmative Motion for Summary Judgment cites case law establishing TPP standing as to all jurisdictions in CPL Subclass A. (*See* Pls.' Mot. for Summ. J., at 37-38 & n.22 (collecting cases)).

Biofuels, LLC v. Hawaiian Elec. Co., 780 F. Supp. 2d 1061, 1074 (D. Haw. 2011) (plaintiff merely need prove that practice "negatively affect[ed] competition" generally). Missouri provides a cause of action to "persons" and defines "persons" to include businesses, but the subject of the lawsuit must be "merchandise *primarily* for personal, family, or household purposes." All of the VCDs at issue in this litigation, as prescription pharmaceutical drugs, were intended for personal consumption by the TPP Health Plans' beneficiaries; accordingly, TPPs as businesses that reimbursed for VCDs that were for personal use by their beneficiaries, have standing under Missouri's CPL.

3. Defendants' Misconstrue the Law on the Applicability of State Law Class Action Restrictions in Federal Court

Defendants'only other argument as to the CPL Subclass A states relates to Louisiana and Montana, both of which contain language indicating to varying degrees restrictions on class actions for their CPL claims. (Mot., at 23-24.) The Supreme Court's *Shady Grove* analysis and follow-on precedent control the outcome of this analysis. 559 U.S. 393, 389-407 (2010) (addressing the conflict between Fed. R. Civ. P. 23 and a state statute prohibiting class action suits and holding, in the plurality decision, with a concurring opinion joining in part, that Rule 23 preempted a New York state law prohibiting class actions in cases seeking penalties and statutory minimum damages).

Courts that have specifically addressed these types of class action restrictions

in CPL statutes since *Shady Grove* have been near unanimous in finding that Rule 23 *categorically* preempts those restrictions in federal diversity cases. *See, e.g., Amato v. Subaru of Am.*, No. 18cv16118, 2021 WL 2154976, at *5-8 (D.N.J. May 27, 2021) (Rodriguez, J.). The court in *Amato* concluded that the Third Circuit had explicitly endorsed Justice Scalia's categorical approach in *Shady Grove* including specifically in the Rule 23 context,[38] and that "it is clear that 'Rule 23, not state law, governs the availbiity of class action treatment" in federal court. *Amato*, 2021 WL 2154976, at *8. Indeed, a federal court in Montana has likewise found that Rule 23 specifically preempts the class action restriction there. *Cross v. Allied Waste Servs. of N.A., LLC*, No. 21cv145, 2023 WL 1778885, at *4 (D. Mt. Jan. 12, 2023). Other courts agree. *Lisk v. Lumber One Preserving, LLC*, 792 F.3d 1331 (11th Cir. 2015)[39];

[38] *See Nuveen Municipal Trust ex rel. Nuveen High Yield Municipal Bond Fund v. WithumSmith Brown, P.C.*, 692 F.3d 283, 302-03 (3d Cir. 2012) (instructing courts to focus not on the state law at issue but rather the substantive or procedural nature of the federal rule, and if the federal rule is procedural and validly implemented pursuant to the Rules Enabling Act, then it categorically preempts any conflicting state law regardless of whether the state law is procedural or substantive); *Knepper v. Rite Aid Corp.*, 675 F.3d 249, 265 (3d Cir. 2012) (applying *Shady Grove* in a FLSA case and finding that "[u]nder the [Shady Grove] plurality's view, any supposed substantive purpose underlying § 216(b) is irrelevant, and we need only determine whether Rule 23 'really regulates procedure,' which the Court has already concluded it does").

[39] After the *Lisk* decision, the Alabama state legislature amended the statute at issue to clarify that its class action restriction in the ADPTA is substantive. Under Justice Scalia's categorical approach, however (as the Third Circuit has adopted), that simply does not matter to the analysis, as a federal district court in Alabama recently found. *Devane v. Walmart Inc.*, No. 2:22cv709, 2023 WL 8881153 (M.D. Ala. Dec.

Albright v. Christensen, 24 F.4th 1039 (6th Cir. 2022); *Martin v. Pierce Cnty.*, 34 F.4th 1125 (9th Cir. 2022).

E. Abundant Evidence of Proximate Cause Exists

Defendants' assertion that the causal chain is too attenuated between their manufacturing contaminated VCDs on the one hand, and Plaintiffs' payments for contaminated VCDs on the other (Defs. Omnibus Mot. at 28-31), is fanciful. Indeed, summary judgment should be granted in Plaintiffs' favor. Defendants do not cite a single fact from any document, deposition, or declaration to support their argument that Plaintiffs cannot prove proximate cause.

The few cases cited by Defendants address proximate cause in the product liability, failure-to-warn context as to whether each physician prescribed the drugs at issue based on the unique circumstances of the patient in weighing the risks and benefits of the drugs they prescribed. *See, e.g., In re Vioxx Prod. Liab. Litig.*, No. MDL 1657, 2010 WL 11570867, at *7 (E.D. La. Mar. 31, 2010) ("Each decision by each doctor and each patient was different."); *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 433-34 (E.D.N.Y. 2009) (similar).

Here, however, no such unique circumstances exist. Defendants marketed and sold their VCDs to every level of purchaser as the generic equivalent to the

22, 2023) ("And this anlaysis [from *Lisk*] does not change despite the ADPTA since being amended to label the class action prohibition as a 'substantive right' ….").

monographed product. But the VCDs were not the equivalent products, and NDMA/NDEA contaminated, adulterated drugs are illegal to sell or prescribe. It is admitted that no company would or should knowingly sell an adulterated drug (*see, e.g.*, ZHP SOMF ¶144) or drugs that contained unsafe levels of NDMA (*see, e.g.*, ZHP SOMF ¶115, 158, 160–61).

Defendants also ignore the fact that other courts have denied motions for summary judgment and upheld verdicts in TPP cases involving pharmaceutical drugs on the issue of proximate causation. *See e.g.*, *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 37, 69, 70 n.12 (1st Cir. 2013) (holding that Kaiser met burden of establishing proximate causation in a prescription drug RICO case: "The doctrine of proximate cause ... protects the ability of primary victims of wrongful conduct to obtain compensation....Here Kaiser was a primary victim.") (citing *BCS Servs., Inc. v. Heartwood 88, LLC,* 637 F.3d 750, 756 (7th Cir.2011)); *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 14 (1st Cir. 2019).

Defendants heavily rely on *Sergents Benevolent Asssociation*, but that case did not involve a contaminated or adulterated drug. It only involved RICO allegations that doctors might not have otherwise prescribed the defendant's drug—which remained on the market—if the defendant did not exaggerate the drug's efficacy. *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 311 (E.D.N.Y. 2014).

In short, no evidence shows any Defendant could or should have sold their adulterated VCDs; to the contrary, Defendants themselves acknowledged that the VCDs were unsaleable. (ZHP SOMF ¶ 143.5, 144, 155-163.2, 167).

F. Defendants' Largely Recycled Damages Arguments Lack Merit

All of Defendants' damages-related arguments, from "no cognizable injury" (Def.' Mot. at 24-28), to their rehashed and previously-rejected attack on Dr. Conti's damages methodology (*id.* at 31-36), to their unsupported assertion that Plaintiffs cannot seek punitive damages (*id.* at 37-43), fall short.

1. Plaintiffs Have Already Established Legally Redressable Injury

Defendants' contention that Plaintiffs "cannot establish a cognizable injury" (Defs.' Mot. at 24) is a thinly-disguised Article III standing argument. The Court already has rejected this exact defense argument multiple times. In MTD Opinion 2 (ECF 728), the Court ruled that all economic loss plaintiffs, including the TPPs currently proceeding to trial, suffered redressable economic injury. *Id.* at 8-15. The Court further rejected Defendants' argument then (the same they make now) that, even if the VCDs were effective for their intended function (lowering blood pressure), "this does not mean Plaintiffs did not suffer an economic injury" *Id.* at 13-14; *see also* ECF 2261, at 38 n.27 (summarizing each side's damages arguments). In certifying the classes, the Court held that the predominant damage issue was amount of damages owed to Plaintiffs and the classes, which was "for the

factfinder." *Id.* The Court additionally ruled that economic worthlessness theory and damages model of Plaintiffs' expert, Dr. Rena Conti, was sufficiently reliable. *Id.* at 86-89. The Court's ruling was consistent with other case law, such as *BCBS v. GlaxoSmithKline*, No. 13-4663, 2019 WL 4751883, at *8-9 (E.D. Pa. Sept. 30, 2019). The Court also distinguished some of the very same inapposite cases that Defendants re-argue now, such as *In Re Rezulin Products Liability Litigation*, 210 F.R.D. 51 (S.D.N.Y. 2002).[40]

Defendants' related claim that Dr. Conti's damages model does not match *any* measure of damages under the pertinent states' fraud or warranty laws (*see* Def. Mem. at 34-37) fares no better. As an initial matter, Defendants are simply incorrect

[40] The other cases Defendants cite now are similarly inapposite. One was an off-label promotion RICO case, in which the plaintiffs (unlike Plaintiffs here) did not allege that the drugs at issue were "unsafe…or somehow worth less than the price paid for the drug." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at *10-*12 (D.N.J. July 10, 2009). In another RICO case, the plaintiffs had "no evidence" that they would not have paid for the drugs at issue, whereas here abundant evidence exists Plaintiffs would not have paid for Defendants' VCDs, among which is the indisputable fact that the VCDs were recalled (and therefore not purchasable) because of the nitrosamine contamination. *See Sergeants Benevolent Ass'n H. & Welfare Fund v. Sanofi-Aventis U.S., LLP*, 20 F. Supp. 3d 305, 334 (E.D.N.Y. 2014). Defendants are also incorrect that Plaintiffs rely on their own experts' say-so that the VCDs were worthless. *See* Defs.' Mot. at 26. To the contrary, Defendants' own admissions (among other things) show that the VCDs were adulterated, contaminated, unmerchantable, and therefore worthless. Defendants' cases on this score also predate the Third Circuit's 2015 holding that overpayment for drugs due to illegal or deceptive marketing practies conssitutes concrete financial loss. *In re Avandia Mktg., Sales Prcs. & Prods. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015).

that some states "only" measure damages under a benefit-of-the-bargain approach or the out-of-pocket approach. To the contrary, at class certification, Plaintiffs and this Court exhaustively analyzed state law, and concluded that the pertinent states allow for *either* measure of damages. *See, e.g.*, ECF 2261 at H-3 ("Alaska allows for either out-of-pocket or benefit-of-the-bargain-damages"), H-13 (Massachusetts "usually" appies benefit-of-the-bargain "except where the plaintiff is content with out-of-pocket damages"). Moreover, Defendants' attempt to gin-up some dispositive difference between benefit-of-the-bargain and out-of-pocket approaches is illusory. As Defendants themselves admit, benefit-of-the-bargain is "the difference between the price paid and the value of the property had the representations been true." Defs.' Mot. at 35 (quotations omitted). They admit out-of-pocket losses are calculated identically: "out-of-pocket damages represent the difference between the price paid and the actual value received." *Id.* at 36 (quotations omitted). Thus, the general approach is the same under either.

2. The Court Already Held That Plaintiffs' Damages Theory and Model Is Sufficiently Reliable

As noted *supra*, the Court already found the damages model of Plaintiffs' expert, Dr. Rena Conti, was sufficiently reliable. *Id.* at 86-89. Nonetheless, Defendants now try for a fourth bite, arguing: (i) a purported mis-match between the subclass definitions and where "point of sale" for VCDs occurred (Defs.' Mot. at 32-34), and (ii) that Dr. Conti's damages model does not fit *any* recognized measure

of damages under the trial subclasses' state laws (*id.* at 34-37). Essentially, these arguments go to class certification, and the reliability and fit of Dr. Conti's opinions. By failing to raise either argument at any prior stage, Defendants likely waived both arguments. *See, e.g.*, *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F. 4 th 651, 679-80 (9th Cir. 2022) (en banc).

Even absent waiver, Defendants' new arguments fail. As to the first, this Court properly defined the subclasses, including the four TPP subclasses selected for trial, as all TPPs that "***paid*** any amount of money **in**" the specified states. ECF 2343 (CMO No. 32) at 1; *see* ECF 2262 & Table 4. Dr. Conti's damages model fits this, as she addressed damages by state, using IQVIA and more recently produced retailer data showing the prices paid by TPPs and consumers at point of sale (i.e., dispensement) in each state.

Defendants' new concoction that "point of sale" does not mean "point of sale," but rather that TPPs "paid" for VCDs at some other point in time or at some other place (*see* Defs.' Mem. at 32-33), is tortured and factually unsupportable. Defendants' own experts, as well as Retailer Defendants who produced actual point-of-sale transactional data, agree that [redacted] Suppl. Teva SOMF ¶ 2-5.

That some after-the-fact adjustments might occur does not alter the point-of-sale payments, and the undisputed reality that TPPs' obligation to pay arises at the

point of sale, and that is the key point in time. *Id*. Indeed, Retailer Defendants' own data produced in this case from the point of sale for VCDs explicitly describes the very amounts used by Dr. Conti as amounts "Ins[urance] Pd" or "TP Paid" or "Payer Pd Amt". *See, e.g.*, ECF 2432 (citing redacted examples); *see also In re Loestrin 24 Fe Antitrust Litig.*, 410 F. Supp. 3d 352, 399 (D.R.I. 2019) (finding "[p]rescription drug transactions are well documented and TPPs have the capability to retrieve information about the drugs they have purchased, the date on which they were purchased, and price paid for the drugs" and "[m]ost TPPs retain PBMs to . . .process claims related to pharmaceutical purchases at pharmacies (i.e., at the point of sale)."); *New England Carpenters H. Benefits Fund v. First DataBank, Inc.*, 248 F.R.D. 363, 369 (D. Mass. 2008) (IMS, now IQVIA, data shows "unit sales and dollar sales (by month, by drug, and by dosage) for transactions reimbursed at retail by (1) TPPs"). The certified subclasses and Dr. Conti's opinions focus on these real-world realities.

Defendants' oblique suggestion that the Court's groupings of state laws was errorenous, *see* Defs.' Mot. at 34, fails for multiple reasons. They already argued state-law variations at class certification. The Court considered the robust record and grouped states' laws based on similarity. Defendants never moved for reconsideration. They also agreed to the subclass groupings for purposes of class notice. *See* ECF 2532 (consent motion to approve notice); ECF 2535 (order granting

same). There is no disconnect that this Court applied the law of plaintiffs' home states at the Rule 12(b)(6) stage before any facts were in the record, but has since defined the classes by reference to where purchases occurred. *See* Defs.' Mot. At 34. Geographically defining a class by reference to where the transaction or payment occurred is commomplace.[41] In any event, Defendants do not proffer any choice-of-law analysis of their own; therefore, they have waived any such argument now (even had they not already argued this at class certification). *See, e.g.*, *Neely v. Club Med Management Services*, 63 F.3d 166, 180 n.10 (3d Cir. 1995) (en banc) ("choice of law issues may be waived").

Finally, Defendants' undeveloped insinuation that the December 1, 2023 amendment to Federal Rule of Evidence 702 warrants reconsideration of the Court's prior *Daubert* ruling (*see* Defs.' Mot. at 27) is spurious. The new amendment merely clarifies the existing standard of expert admissibility, which this Court already applied correctly in evaluating the reliability of the methodology leading to the

[41] *See, e.g.*, *In re Santa Fe Natural Tobacco Co. Mktg. & Sales Pracs. & Prods. Liab. Litig.*, MD 16-2695, 2023 WL 6121894, at *176 (D.N.M. Sept. 19, 2023) (defining many subclasses in MDL by references to purchases in each specified state); *In re Flonase Antitrust Litig.*, 85 F. Supp. 2d 867, 882-84 (E.D. Pa. 2011) (denying summary judgment on TPP class claims grouped by state of purchase of drug); *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 135 (E.D. Pa. 2011) (The place of purchase is where the relationship between the parties is centered; it is where the transaction with the alleged overcharge [for a drug] actually occurs."); *Allen v. Holiday Universal*, 249 F.R.D. 166, 194 (E.D. Pa. 2008) (defining class as all purchasers who entered transaction in given state).

opinions. The amendment does not alter existing law and does not "impose[] any new, specific procedures." Fed. R. Evid. 702, advisory committee's note to 2023 amendment. Relatedly, Defendants' two snippets from Dr. Conti's July 2023 deposition (Defs.' Mot. at 28) hardly constitute concessions, let alone ones precluding Plaintiffs from any recovery as a matter of law. The excerpted testimony is completely consistent with Dr. Conti's long-maintained opinions that adulterated drugs have no economic value because they cannot be sold, *see, e.g.*, ECF 2261 at 20-23 (acknowledging plaintiffs' theory), which also is consonant with defense testimony that they cannot sell adulterated product and the pills could not be sold due to the contamination. *See, e.g.*, ZHP SOMF ¶ 139, 143, 155, 159, 163.1; Teva SOMF ¶ 25; Torrent SOMF ¶ 49, 57.

G. Plaintiffs Are Entitled to Put Punitive Damages to the Factfinder

Plaintiffs have viable claims for punitive damages for their express warranry, common law fraud, and CPL claims for the states at issue in this trial.

1. Choice of Law for Punitive Damages

Defendants argue that "punitive damages should be governed by the law where the TPPs are based" (Defs. Omnibus Mot. at 37), but New Jersey's choice-of-law rules dictate otherwise. *See Powell v. Subaru of Am., Inc*., 502 F. Supp. 3d 856, 875 (D.N.J. 2020) ("When conducting a choice of law analysis, New Jersey uses the 'most significant relationship' test of the Restatement (Second) of Conflict of

Laws).”). Even assuming New Jersey law does not apply to all claims (as nearly all trial defendants are headquartered here), while the home state of the plaintiff is sometimes relevant to the choice-of-law analysis, here the states that have the most significant relationship to the TPPs’ claims are not their home states, but the states where VCDs were purchased by consumers and paid for by TPPs on their behalf. *See* Restatement (Second) of Conflict of Laws §§ 145, 148, 188; *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig*., 335 F.R.D. 1, 35 (E.D.N.Y. 2020) (“[T]he law of the TPPs’ insured consumer’s place of purchase governs the TPPs’ claims under the most significant relationship test and the government interest test … [W]ithout a consumer’s purchase in that state, the TPP would not be injured.”); *In re Wellbutrin XL Antitrust Litig*., 282 F.R.D. 126, 135 (E.D. Pa. 2011) (While “[t]he home state of a TPP undeniably has a strong interest in transactions that affect the TPP,” the “place of purchase is where the relationship between the parties is centered … A place-of-purchase rule protects justified expectations because an in-state transaction will be governed by the antitrust laws and/or consumer protection laws of that state and not by the chance location of the TPP’s principal place of business ….”). The proper choice of law for punitive damages is the law of the states at the point of sale where consumers purchased VCDs and they were paid for largely by TPPs on their behalf. Just as those laws apply to the underlying claims of breach of express warranty, consumer fraud, and fraud, so too do they apply to

TPPs' claims for punitive damages.

2. Availability of Punitive Damages for Claims Plaintiffs Assert

Punitive damages are permissible as remedies in several states in TPP Breach of Express Warranty Subclass Group b.[42] Similarly, punitive damages are available

[42] *See e.g., Stein v. Lukas*, 923 S.W. 2d 832, 834-36 (**Ark**. 1992); *Todd v. Kellum,* No. 15cv00177, 2016 WL 4261919, at *3 (N.D. Miss. Aug. 10, 2016) ("Furthermore, in 'rare instances,' **Mississippi** law allows punitive damages for breach-of-warranty claims. Specifically, punitive damages may be allowed when "[i]n addition to the breach, 'there ... enter[s] into the injury some element of aggression or some coloring of insult, malice or gross negligence, evincing ruthless disregard for the rights of others, so as to take the case out of the ordinary rule.'"); *Textana, Inc. v. Klabzuba Oil & Gas*, 222 P.3d at 590 (Mt. 2009) (Punitive damages are recoverable under **Montana** law where the claimant 'proves by clear and convincing evidence that the defendant is guilty of actual fraud or actual malice outside the contract context. (internal quotations and citation omitted)); *Bristol Vill., Inc. v. Louisiana-Pac. Corp*., 916 F. Supp. 2d 357, 371 (W.D.N.Y. 2013) ("Further, punitive damages for the breach of contractual obligations, such as express warranties, are generally unavailable unless necessary to vindicate a public right. Punitive damages are recoverable in contract claims where the breach involved particularly egregious fraud aimed at the public generally." (internal citations omitted)); *Baker v. Knott*, No. C.A. NO. 77-442, 1980 WL 336061, at *9–10 (R.I. Super. May 27, 1980) (**Rhode Island** court awarding punitive damages in case of "breach of warranty accompanied by deceit"); *Murphy v. Stowe Club Highlands,* 761 A.2d 688, 696 (Vt. 2000) (under **Vermont** law, "Punitive damages are generally not recoverable in actions for breach of contract. However, in certain extraordinary cases in which the breach has the character of a wilful and wanton or fraudulent tort, punitive damages may be allowed. Punitive damages are awarded not as compensation to the sufferer, but "on account of the bad spirit and wrong intention" of the breachor."). Also, Defendants concede that "four of the warranty subclass states' laws apparently do permit recovery of punitive damages" (Defs.' Mot., at 39-40)(citing cases from **Arkansas, New York, Ohio and Mississippi**).

for Plaintiffs' CPL claims[43] and common law fraud claims.[44]

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[43] Civil Penalties are generally available for consumer fraud actions. Alask. Stat. §§ 45.50.531 (In **Alaska**, "three times actual damages or $500, whichever is greater"); Conn. Gen. Stat. Ann. § 42-110g (court may award punitive damages); Haw. Stat. § 480-13(1) (under **Hawaii** law, "not less than $1,000 or threefold damages by the plaintiff sustained, whichever is greater"); Mo. Rev. Stat. § 407.025 (**Missouri**: "The court may, in its discretion: (1) award punitive damages."); Neb. Rev. Stat. Ann. § 59-1609 (**Nebraska**: "[A]nd the court may in its discretion, increase the award of damages to an amount which bears a reasonable relation to the actual damages which have been sustained and which damages are not susceptible of measurement by ordinary pecuniary standards; except that such increased award for violation of section 59-1602 shall not exceed one thousand dollars"); N.H. Rev. Stat. § 358-A:10 (**New Hampshire**: "If the court finds that the use of the method of competition or the act or practice was a willful or knowing violation of this chapter, it shall award as much as 3 times, but not less than 2 times, such amount."); N.Y. Gen. Bus. Law § 349 (**New York:** "The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the defendant willfully or knowingly violated this section. "); N.C. Gen. Stat.§ 75-16 (**North Carolina** provides for trebling damages); Or. Rev. Stat. Ann. § 646.638 ("The court or the jury may award punitive damages"); 73 Pa. Cons. Stat. § 201-9.2 (up to three times actual damages under **Pennsylvania** law); Wash. Code Rev. 19.86.090 (treble damages available under **Washington** law).

[44] *Brady v. E&Y Dev., Inc.,* No. 3:07-CV-00245-TMB, 2010 WL 11512284, at *5 (D. Alaska July 29, 2010) (punitive damages may be awarded under **Alaska** law for intentional torts); *Holiday Inn Franchising, Inc. v. Hotel Assocs*., Inc., 2011 Ark. App. 147, 17, 382 S.W.3d 6, 17 (2011) ("such deliberate deceit in the context of a [**Arkansas**] fraud claim warrants submission of punitive damages to the jury"); *Grays v. Auto Mart USA, LLC*, No. 18-CV-01761-MSK-NYW, 2020 WL 13219891, at *8 (D. Colo. Apr. 17, 2020) ("**Colo**. Rev. Stat. § 13-21-102 expressly contemplates punitive damages may be appropriate for civil actions where the injury claimed 'is attended by circumstances of fraud.'"); *Washington Medical Ctr. v. Holle*, 573 A.2d 1269, 1284 (D.C. 1990) ("[P]unitive damages [under **D.C.** law] are warranted only when the defendant commits a tortious act accompanied with fraud, ill will, recklessness, wantonness, oppressiveness, willful disregard of the plaintiff's right, or other circumstances tending to aggravate the injury."); *W.R. Grace & Co.—Conn. v. Waters*, 638 So. 2d 502, 503 (Fla. 1994) ("Punitive damages are appropriate [under **Florida** law] when a defendant engages in conduct which is fraudulent,

malicious, deliberately violent or oppressive, or committed with such gross negligence as to indicate a wanton disregard for the rights of others."); *Alexander v. Stibal*, 161 Idaho 253, 265, 385 P.3d 431, 443 (2016) ("**Idaho** Code section 6-1604(1) authorizes an award of punitive damages for fraudulent conduct."); *C. Mac Chambers Co. v. Iowa Tae Kwon Do Academy, Inc.*, 412 N.W.2d 593, 599 (**Iowa** 1987) ("punitive damages may be awarded where a defendant is found guilty of fraud."); *Thomas v. Bridges*, 2013-1855 (La. 5/7/14), 144 So. 3d 1001, 1009 (2014) ("[F]raud is a serious accusation of intentional deceit which, in most contexts, merits award of additional penalties or punitive damages.")); *Xiaolin Li v. Franchoice, Inc.*, Case No. 19-cv-1267, 2020 WL 2192325, at *9 (D.Minn. May 6, 2020) (Under **Minnesota** law, punitive "damages are appropriate in the context of fraud."); *Nappe v. Anschelewitz, Barr, Ansell & Bonello*, 477 A.2d 1224, 1231 (N.J. 1984) ("Moreover, it is especially fitting to allow punitive damages for actions such as legal fraud [under **New Jersey** law], since intent rather than mere negligence is the requisite state of mind."); *Solutia Inc. v. FMC Corp*, 466 F. Supp. 2d 429, 453 (S.D.N.Y. 2006)("**New York** law provides that fraudulent conduct may give rise to punitive damages."); N.C. Gen. Stat. § 1D-15(a)(1) (**North Carolina** statute: "Punitive damages may be awarded only if the claimant proves that the defendant is liable for compensatory damages and that one of the following aggravating factors was present and was related to the injury for which compensatory damages were awarded: (1) Fraud."); N.D. Cent. Code § 32-03.2-11 (**North Dakota** statute: "**When court or jury may give exemplary damages.** In any action for the breach of an obligation not arising from contract, when the defendant has been guilty by clear and convincing evidence of . . . fraud, . . . , the court or jury, in addition to the actual damages, may give damages for the sake of example and by way of punishing the defendant."); *Windsor Med. Ctr., Inc. v. Time Warner Cable, Inc.*, 2021-Ohio-158, ¶ 38, 167 N.E.3d 23, 31 ("In cases alleging fraud [under **Ohio** law], in order to be awarded punitive damages, the plaintiff must establish not only the elements of the tort itself, but must also show either the fraud is aggravated by the existence of malice or ill, or must demonstrate the wrongdoing is particularly gross or egregious.") (internal citations omitted); *Okland Oil Co. v. Conoco Inc.*, 144 F.3d 1308, 1314 (10th Cir. 1998) ("The jury found [Defendant] separately liable for the torts of fraud and deceit, both of which may support an award of punitive damages under **Oklahoma** law."); *N. Atl. Fishing, Inc. v. Geremia*, 153 B.R. 607, 613 (D.R.I. 1993) ("under **Rhode Island** law, a court may only award punitive damages for intentional conduct that is malicious.") (internal citations omitted); *Dziadek v. Charter Oak Fire Ins. Co.*, 867 F.3d 1003, 1011 (8th Cir. 2017) ("**South Dakota** Law § 21–3–2 authorizes punitive damages when there is evidence of 'oppression,

3. *Plaintiffs Can Satisfy the Punitive Damages Standards of All States that Allow Them Based on the Facts of this Case*

The essential requirement under all states for the award of punitive damages is that the defendant acted maliciously, fraudulently or with willful and wanton disregard for the rights or safety of others.[45] Plaintiffs can meet the standard for

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fraud, or malice.'") (internal citations omitted); *Rousseau v. Coates*, 488 F. Supp. 3d 163, 169 (D. Vt. 2020) ("**Vermont** law plainly allows punitive damages in the context of a fraud claim"); *Adkins v. Crown Auto, Inc.*, 488 F.3d 225, 234 (4th Cir. 2007) ("In **Virginia**, punitive damages may be recovered on a common law fraud claim . . . only upon proof, either direct or circumstantial, showing actual malice."); *Alexander v. Meduna*, 47 P.3d 206, 218-20 (Wyo. 2002) (affirming an award of punitive damages based on the sellers' deception and fraud).

[45] *See* **Alabama:** Ala. Code § 6-11-20(a); **California**: Cal. Civ. Code § 3294(a); **Connecticut**: *Vandersluis v. Weil*, 176 Conn. 353, 358, 407 A.2d 982, 986 (1978); **District of Columbia**: *Dist. Cablevision Ltd. P'shp v. Bassin*, 828 A.2d 714, 725 (D.C. 2003); **Florida:** Fla. Stat. Ann. § 768.72(2); **Georgia**: O.C.G.A. § 51-12-5.1(b); **Hawaii**: Hawai'i Jury Instructions, Instruction No. 8.12, *available at* https://www.courts.state.hi.us/docs/legal_references/jury_instructions_civil.pdf; **Idaho**: Idaho Code § 6-1604(1); **Illinois**: *Home Sav. & Loan Asso. v. Schneider*, 108 Ill. 2d 277, 284, 91 Ill. Dec. 590, 593, 483 N.E.2d 1225, 1228 (1985); **Iowa:** *Cawthorn v. Catholic Health Initiatives Iowa Corp.*, 743 N.W.2d 525, 528 (Iowa 2007); **Massachusetts**: *Haddad v. Wal-Mart Stores, Inc.*, 455 Mass. 91, 107, 914 N.E.2d 59, 72 (2009); **Minnesota**: *L.M. ex rel. S.M. v. Karlson*, 646 N.W.2d 537, 546 (Minn. Ct. App. 2002); **Mississippi**: Miss. Code Ann. § 11-1-65(1)(a); **Missouri**: *Waters v. Ferrara Candy Co.*, No. 4:17-cv-00197-NCC, 2017 U.S. Dist. LEXIS 92915, at *8 (E.D. Mo. June 16, 2017); **Montana**: Mont. Code Ann. § 27-1-221; **New Hampshire**: N.H. Rev. Stat. Ann. § 358-A:10; **New Jersey**: *Rivera v. Valley Hosp., Inc.*, 252 N.J. 1, 17–18, 280 A.3d 299, 309–10 (2022); **New York**: *Marinaccio v. Town of Clarence*, 20 N.Y.3d 506, 511, 986 N.E.2d 903, 906 (2013); **North Carolina**: *Est. of Long by & through Long v. Fowler*, 2021-NCSC-81, ¶ 32, 378 N.C. 138, 150–51, 861 S.E.2d 686, 696 (N.C. 2021); **North Dakota**: *Thimjon Farms Partnership v. First International Bank & Trust*, 837 N.W.2d 327, 340 (N.D. 2021); **Ohio**: *McHenry v. McHenry*, 2017-Ohio-1534, ¶ 73, 88 N.E.3d 1222, 1234; **Oklahoma**: *Estrada v. Port City Properties, Inc.*,

punitive damages in each of the relevant states based on the facts before the Court.

The conduct exhibited by the Trial Defendants is discussed in detail in the Defendant specific briefs filed by Plaintiffs. In short, ZHP demonstrated a conscious, malicious, willful and wanton disregard for the safety of, and economic harm to others when it made a deliberate choice to continue manufacturing and selling its contaminated valsartan, fully knowing that NDMA and NDEA are probable human carcinogens. (ZHP SOMF ¶ 35-42.5). Torrent's conduct evidences a similar level of malice. It consciously disregarded the rights and safety of others when it learned of the risk of impurities and, most egregiously, after receiving notice that it was selling ZHP's adulterated valsartan. At that moment, Torrent unequivocally knew that it was selling not only a worthless product, but one contaminated with a probable human carcinogen.

For its part, Teva was well-aware of serious cGMP violations at ZHP for years, yet deliberately turned a blind eye. *See* ECF 2569, at 16-18; ECF 2566, at ¶ 29-34, 42-96, 109-122. [redacted]

2011 OK 30, 258 P.3d 495, 502, n. 21; *see also* Okla. Stat. tit. 23, § 9.1; **Oregon**: Or. Rev. Stat. § 31.730(1); **Rhode Island**: *Felkner v. Rhode Island Coll.*, 203 A.3d 433, 461 (R.I. 2019); **South Dakota**: *Fluth v. Schoenfelder Constr., Inc.*, 2018 S.D. 65, ¶ 31, 917 N.W.2d 524, 533–34; **Utah**: *Diversified Striping Sys. Inc. v. Kraus*, 2022 UT App 91, ¶ 98, 516 P.3d 306, 327; **Virginia**: *City-to-City Auto Sales, LLC v. Harris*, 78 Va. App. 334, 350–51, 891 S.E.2d 396, 404 (2023); **Vermont**: *Beaudoin on Behalf of New England Expedition Ltd. P'ship II v. Feldman*, 2018 VT 83, ¶ 18, 208 Vt. 169, 178, 196 A.3d 768, 776 (2018); **Wyoming**: *Cramer v. Powder River Coal, LLC*, 2009 WY 45, ¶ 17, 204 P.3d 974, 979–80 (Wyo. 2009).

[redacted] (ECF 2566, at ¶ 1-5, 42-55), [redacted]

III. CONCLUSION

For the foregoing reasons, the Court should reject Defendants' omnibus motion for summary judgment.

Dated: January 22, 2024

Respectfully submitted,

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